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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT	PAPER NUMBER
	3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/695,067	YOUNG ET AL.	
	Examiner	Art Unit	
	Jerry Cumberledge	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 December 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-58 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-58 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 28 October 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments, see page 10, third paragraph (arguments regarding treating the first shaft and the first rod connector as the same component), filed 12/15/2006 have been fully considered and are persuasive. To further clarify the Examiner's position regarding the claims, the following Office Action is being presented. Also, upon further consideration, a new reference is being presented in this Office Action regarding claim 56 (Burgess et al., US Pub. 2003/0114853 A1).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6, 10-15 and 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "the first rod connecting portion" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 10, line 1 recites "...the shaft is slidable received..." Appropriate correction is required.

Claim 22, line 1 recites "...the shaft is slidable received..." Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

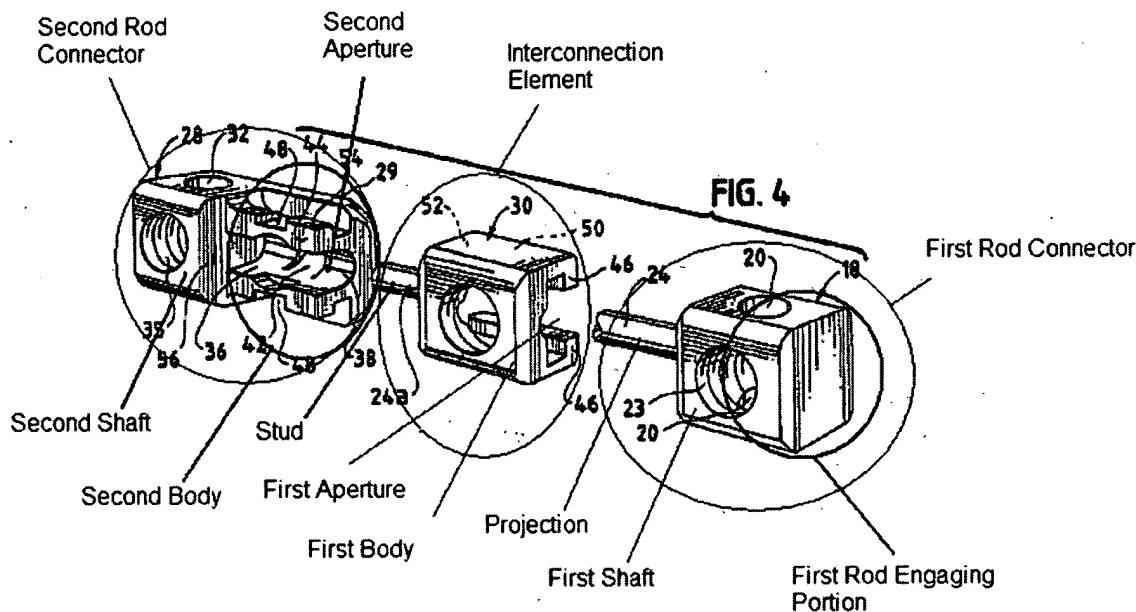
Claims 1-23, 29-34, 43-53 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Korhonen et al. (US Pat. 5,669,910).

Korhonen et al. disclose a cross-connector assembly for interconnecting a pair of orthopedic rods (Fig. 4, below), said assembly comprising: an interconnection element including a first body having a first aperture formed therein and a stud extending from the body; a first rod connector including a first shaft terminating in a first rod engaging portion and a projection extending laterally from said first shaft and displaced axially along said first shaft from the spinal rod engaging portion, said first shaft and said projection slideably received within the first aperture; a second rod connector including a second shaft having a second body carried thereon, said second body having a second aperture formed therein, said second aperture having the stud received therein; and a fastener configured to engage with the stud (Fig. 2, ref. 34). The first aperture defines a first axis (Fig. 4, the axis that extends from near bottom ref. 46 to near top ref. 46, along the rectangular portion of the aperture) extending through the first body and the stud is positioned to lie substantially orthogonal to the axis (Fig. 4, below). The first aperture is non-circular, since it has a rectangular component (Fig. 4, near bottom ref. 46 to near top ref. 46). The first shaft exhibits a substantially round cross-sectional

profile (Fig. 4). The first rod connecting portion comprises a curved member configured to at least partially encircle a spinal rod, since the rod engaging portion has curves near ref. 20 and ref. 23, which can be used to encircle a spinal rod. The first rod connecting portion comprises a threaded aperture (Fig. 4, ref. 23) extending into the curved member. The first shaft is substantially straight (Fig. 4). The first shaft is curved so as to be non-linear, since it has rounded edges. The second shaft is curved, since it has rounded edges. The first shaft is slidable received within the first aperture to allow the first rod engaging portion to be spaced from the second rod engaging portion at varying distances. The second shaft is rotatable about an axis formed by the stud to vary an angle defined by the first shaft and the second shaft. The first shaft and the second shaft are curved, since they have rounded edges. The second aperture of the second shaft is configured to allow the second shaft to pivot along the axis defined by the stud. The first rod connector is rotatable about an axis defined by the first shaft. The second body on the second shaft includes a lower surface (Fig 4, surface near ref. 38), wherein engagement of the fastener to the stud urges the lower surface to contact the first shaft and clamp the fast shaft in a first orientation relative to the second shaft. The first rod connector is rotatable about an axis defined by the first shaft. Rotation of the first rod connector induces the projection to contact said first body and inhibit removal of the first shaft from the first aperture. The first rod connector is rotatable about an axis defined by the stud. The second rod connector is rotatable about an axis defined by the stud. The first shaft of the first rod connector and the second shaft of the second rod connector are curved, since they have rounded edges. The first shaft is slidable received within

the first aperture to allow the first rod engaging portion to be spaced from the second rod engaging portion at varying distances. The assembly further comprises a first spinal rod (Fig. 1, ref. 12) secured to the first rod engaging portion (Fig. 1) and a second spinal rod (Fig. 1, ref. 14) secured to the second rod engaging portion, wherein the first spinal rod is positioned to lie non-parallel to the second spinal rod. Engagement of the fastener to the stud induces the washer to deform. Engagement of the fastener frictionally engages the washer to the first shaft of the first rod connector. Engagement of the fastener to the stud secures the second rod connector in a selected orientation. The first spinal rod defines a first plane and the second spinal rod is positioned to lie in a plane different from the first plane. The first rod engaging portion comprises a hook sized to at least partially encircle a spinal rod, said hook extending laterally from the first shaft in a first direction and wherein said projection extends laterally from the first shaft along said first direction. The definition of hook, according to the Merriam-Webster Online Dictionary, is "a curved or bent device for catching, holding or pulling." The rod engaging portion can be considered to be a hook, because it has curves (around the circular bores), and it is used for holding the rod. It is extending laterally from the shaft, since it is coming from the side of the shaft (Fig. 4). The projection defines a finger, lobe, or ridge. The projection can be considered to be a finger. At least one of the first shaft or the second shaft has a smooth exterior surface (Fig. 4) and a round or oval cross-sectional profile (Fig. 4). The first and second shafts are configured to nest with each other (Fig. 2).

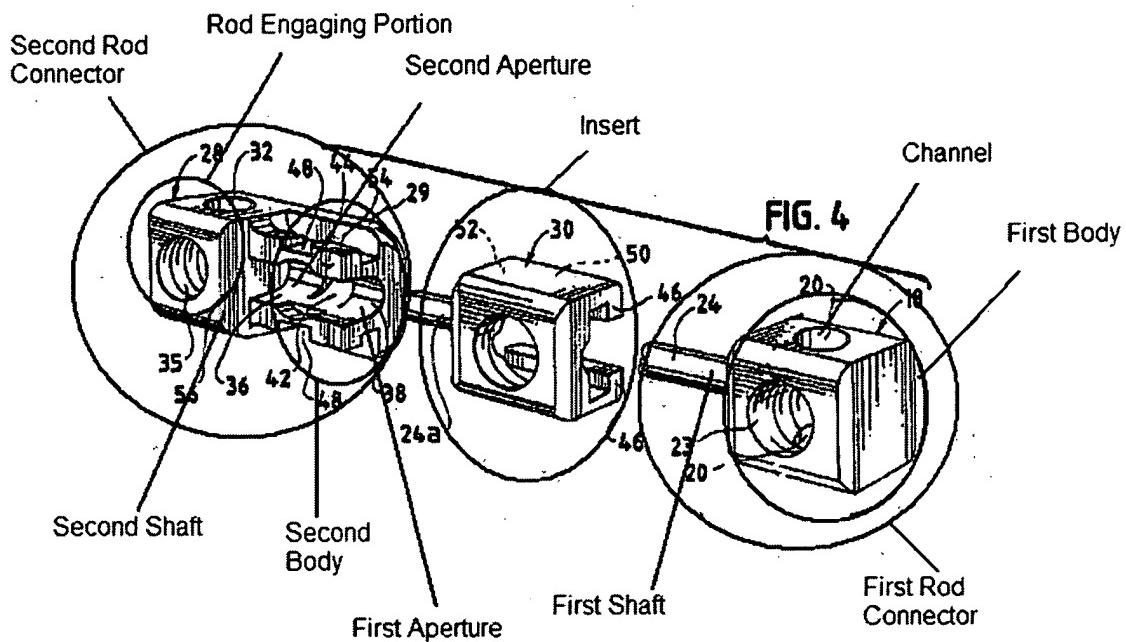
Korhonen et al. disclose a method of treating a spinal defect, said method comprising: securing a first spinal rod and a second spinal rod each to two or more vertebrae; and interconnecting the first spinal rod to the second spinal rod using the assembly of claim I (column 3, lines 16-22).



Korhonen et al. disclose a cross-connector assembly (Fig. 4, below) for interconnecting a pair of orthopedic rods, said assembly comprising: a first rod connector including a first shaft terminating in a first body having a channel therethrough a second rod connector including a second shaft defining a longitudinal axis and terminating on a first end with a rod engaging portion and on an opposite second end with a second body, said second body having a first aperture therein defining a first central axis positioned to lie in a plane with the longitudinal axis, said

second rod connector also including a second aperture therein defining a second central axis positioned to lie at an angle to the first central axis; an insert configured to engage the first shaft of the first rod connecting member extending through the first aperture and positioned in said second body and in communication with said second aperture; and a fastener (Fig. 2, ref. 41) extending through the second aperture of the second body and engaging one or more of the insert (Fig. 2, ref. 41), the second body of the second rod connector, or the first shaft of the first rod to secure the orientation of the first rod connector relative to the second rod connector. The first shaft of the first connector is straight (Fig. 4). The first shaft of the first connector is curved, since it has rounded edges (Fig. 4). The first aperture and the second aperture intersect (Fig. 4). The fastener engages with both the insert and the first shaft. The fastener engages the insert thereby securing the first rod connecting member in a desired orientation relative to the second rod connecting member. The fastener engages the first shaft thereby securing the first rod connecting member in a desired orientation relative to the second rod connecting member. The fastener engages the second body of the second rod connector thereby securing the first rod connecting member in a desired orientation relative to the second rod connecting member.

Korhonen et al. disclose a method of treating a spinal defect, said method comprising: securing a first spinal rod and a second spinal rod each to two or more vertebrae; and interconnecting the first spinal rod to the second spinal rod using the assembly of claim 44 (column 3, lines 16-22).

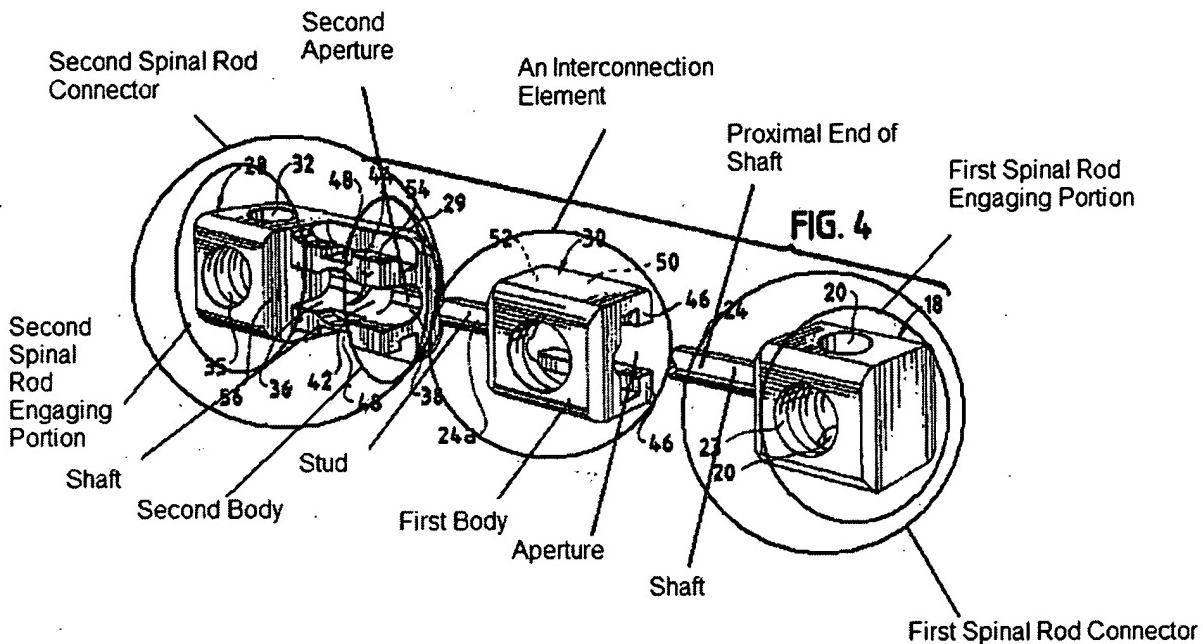


Korhonen et al. disclose an cross connector (Fig. 4, below) comprising an interconnection element including a first body having an aperture formed therein and a stud extending from said body; a first spinal rod connector including a first shaft having a proximal end received within said aperture and a distal end carrying a first spinal rod engaging portion configured to at least partially encircle a spinal rod; a second spinal rod connector having a second body on a proximal end, a second spinal rod engaging portion on a distal end and a second shaft extending therebetween , wherein said body includes a second aperture having the stud received therein; and a single fastener (Fig. 2, ref. 41) to secure the first and second spinal rod connectors to each other at a user defined orientation relative to each other.

Korhonen et al. disclose a method of treating a spinal defect, said method comprising: securing a first spinal rod and a second spinal rod each to two or more

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vertebrae; and interconnecting the first spinal rod to the second spinal rod using the assembly of claim 53 (column 3, lines 16-22).



With regard to the statements of intended use and other functional statements (e.g. ...the first shaft is slidably received within the first aperture..., ..., the second shaft is rotatable about an axis formed by the stud..., ...configured to allow the second shaft to pivot..., ...rotation of the first rod connector induces the projection to contact said first body...,etc.), they do not impose any structural limitations on the claims distinguishable over the device of Korhonen et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that

the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 35, 36, 39-42, 54, 55 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korhonen et al. (US Pat. 5,669,910) in view of Schluzas (US Pat. 6,554,832 B2).

Korhonen et al. disclose the claimed invention, except for an insert, and the insert and the first aperture defining a ball and socket joint.

Schluzas discloses a cross-connector assembly with an insert (Fig. 2, ref 48) and a first aperture (Fig. 2, near ref. 50), and the insert and the first aperture forming a ball and socket joint (Fig. 4), in order to allow the connecting rod to pivot (column 2, lines 36-39) and conform to the specific area of the spine that is being stabilized (Fig. 1). The insert is configured to at least partially encircle the first shaft (Fig. 2, ref. 52 and 42). The insert is configured to at least partially encircle the stud, since the stud and the

first shaft have approximately same diameter (Korhonen et al., Fig. 2). The insert can be placed in the second aperture to define a ball and socket joint, similar to the ball and socket joint of the first aperture. The insert is substantially spherical on one end (Fig. 2, ref 50) and substantially cylindrical on the other end (Fig. 2, the end near ref. 40). The insert in combination with the first body can restrict movement of the first shaft to inhibit disassembly of the apparatus. The insert can be positioned within the second body and is configured to at least partially encircle the second shaft. The insert allows the connecting rod to pivot and to conform to the specific area of the spine that is being stabilized (Fig. 1).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the cross-connector assembly of Korhonen et al. with the insert (Fig. 2, ref. 48) and first aperture (Fig. 2, near ref. 50) of Schluzas, and the insert and the first aperture forming a ball and socket joint (Fig. 4) of Schluzas, in order to allow the connecting rod to pivot (column 2, lines 36-39) and conform to the specific area of the spine that is being stabilized (Fig. 1).

Claims 24-28, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korhonen et al. (US Pat. 5,669,910) in view of Sherman et al. (US Pat. 5,976,135).

Korhonen et al. disclose the claimed invention except for the washer and the washer having splines and the second spinal rod connector having a lower surface, which has a second set of splines.

Sherman et al. disclose a lateral connector assembly comprising a washer (Fig. 7, ref. 55) and the washer having splines (Fig. 7, ref. 60) and recesses (Fig. 6, ref. 58) and the second spinal rod connector having a lower surface (Fig. 11, ref. 72), which has a second set of splines (Fig. 11, ref. 82) which can matingly engage the splines of the washer, which allow the lateral connector to assume variable angular positions with respect to the washer (column 7, lines 1-19). The washer is made from a deformable material, since any material will deform when pressure is applied to it. The washer is capable of deforming when the fastener engages the stud. Engagement of the fastener can frictionally engage the washer to the first shaft of the first rod connector. The washer is capable of being carried by the stud and positioned between the stud and the second aperture of the second rod connecting member. This set-up enables the lateral connector to assume variable angular positions with respect to the washer (column 7, lines 1-19).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the cross-connector assembly of Korhonen et al. with the a washer and the washer having splines and the second spinal rod connector with a lower surface, which has a second set of splines of Sherman et al., in order to allow the lateral connector to assume variable angular positions with respect to the washer (column 7, lines 1-19).

Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Korhonen et al. (US Pat. 5,669,910) in view of Burgess et al. (US Pub. 2003/0114853 A1).

Korhonen et al. disclose the claimed invention except for the first shaft comprising a protuberance extending laterally therefrom, said protuberance sized to be received within said first aperture.

Burgess et al. disclose a cross connector (Fig. 3, refs. 20 and 16) with a shaft (Fig. 3, ref. 14) comprising a protuberance (Fig. 3, ref. 28) extending laterally therefrom (best seen in Figs. 2 and 4), the protuberance being sized to be received with an aperture (Fig. 3, ref. 30), the protuberance and its corresponding mating surface allow for movement in three degrees of freedom over one another (paragraph 0008, lines 5-7).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the first shaft of Korhonen et al. with a protuberance extending laterally therefrom as taught by Burgess et al., in order to allow the first shaft and the aperture in which it is found to move in three degrees of freedom relative to each other (paragraph 0008, lines 5-7).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571)

272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



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SUPERVISORY PATENT EXAMINER